CMS to Test Enhanced Medication **Therapy Management Model**

Aims for Greater Use of Pharmacists, Cost Savings, and Better Outcomes

Stephen Barlas

etter integration of pharmacists into the Medicare Part D Medication Therapy Management (MTM) program is one of the objectives of the new test model starting in five regions in 2017.1 The new Enhanced MTM (EMTM) model is the major initiative the Centers for Medicare and Medicaid Services (CMS) has authorized for the Part D outpatient drug program in 2017, although there will be some tweaks beyond

the EMTM test period. The new model represents a major first-time move into the "value" health care space for the Medicare Part D program. The model will test whether high-quality medication management can save the federal government money and provide seniors with better health and fewer hospitalizations.

The EMTM model, which prescription drug plans (PDPs)—the Part D outpatient drug companies must apply for, is an effort to breathe life into MTM programs that have severely underperformed since

the Part D benefit went into effect in 2006. Pharmacists have been clamoring for years for more involvement in MTM programs generally and for reimbursement for those services. The current PDP MTM programs are almost exclusively run in-house, with the PDPs hiring pharmacists or nurses to make phone calls to eligible plan members. However, there is a niche group of MTM service vendors that have cropped up in the past decade or so: PDPs occasionally contract with those companies. They typically do have local pharmacy networks, but the CMS has acknowledged that few Part D MTM plans reach down to the patient's physician or local pharmacist in an effort to coordinate information flow. The PDPs argue there aren't enough incentives to make them expand their programs.

Larry Kocot, Principal and National Leader of the KPMG Center for Healthcare Regulatory Insight, believes the EMTM model has the potential to be a "game changer," as it realigns the incentives in Part D to encourage plans to promote higherquality pharmacy care at a lower overall plan cost. Kocot was Senior Advisor to the Administrator of the CMS during the implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The CMS will provide the investment for each company. Kocot calls the EMTM model funding "free money for plans to invest in new, more targeted interventions that should produce better evidence on the most effective MTM programs." By providing this extra funding, the CMS is hoping that participating plans will be able to reduce Part A and B Medicare costs by

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more than 2% for their entire Part D population, including those members outside the EMTM model. If, at the end of five years, a PDP has met that goal, the CMS will reward the PDP with a \$2 per member per month (PMPM) premium subsidy that will be applied to lower plan premiums, which will make the successful PDPs even more competitive in the future. Companies that run a model program will not run a

conventional MTM program.

Besides the separate payment for the carve-out test and the potential \$2 PMPM on the back end, the key elements of the model include the ability to offer different MTM services to individuals based on their level of medication-related risk with interventions tailored to those enrollees' specific barriers to improvement, including cost-sharing assistance to beneficiaries who need it. One incentive not being offered is Medicare reimbursement for pharmacists. Theoretically, the PDPs can pay pharmacists for

Stephen Barlas their participation. Whether they will or they won't is unclear.

No PDPs have announced their participation in the enhanced model. The deadline for submitting applications has passed, and the CMS has not made public the number of applications, nor have any contracts been issued. William Polglase, a CMS spokesman, declined to provide any details on applications received or when approvals will be announced. The agency is in the progress of providing information on the data PDPs will have to collect and how they will have to submit that data, which will report on three monitoring measures:

- Percentage of beneficiaries discharged from the hospital who received EMTM services
- 2. Percentage of targeted beneficiaries with at least one medication therapy issue
- 3. Percentage of MTM recommendations that are implemented

Jessica Frank, Vice President of Quality for Outcomes MTM, says many of the Part D stand-alone plans her company has consulted with in the five regions have submitted applications to participate in the enhanced model. "A large driving factor is that they will not be able to submit applications after the first year," she explains. Health plans contract with her company, which works with a network of community pharmacists that provides the MTM services requested by the health plan. Pharmacies don't pay to become part of the Personal Pharmacist Network. OutcomesMTM also has a backup telephonic team for instances where plan members are beyond the reach of the retail pharmacies in the network.

But some Part D plans are giving the model test a cold

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shoulder. EnvisionRx, a pharmacy benefit manager (PBM) that became part of Rite Aid last year, is one of them. EnvisionRx offers plans in some of the five pilot regions. "When we analyzed the specific regions offered, and considered those relative to the CMS parameters and requirements for the pilot, we chose not to apply," explains Bobby Creek, Vice President of Marketing at EnvisionRx.

Some Major Challenges for Prospective Participants

One of the new features that has given pause to PDPs and PBMs is the requirement that PDPs submit data on the three monitoring measures in Systematized Nomenclature of Medicine–Clinical Terms (SNOMED CT) codes, a standardized nomenclature set, which allows electronic submission. Additional details related to those codes won't be available until July 2016, when the CMS expects to publish the final EMTM encounter data specifications and pilot monitoring measures. Use of SNOMED CT codes requires software adjustments for the PDPs and probably even greater adjustments and costs for pharmacists and physicians whom the CMS hopes the PDPs will engage.

In a February 28, 2016, memorandum to PDPs, Gregory Woods, Director of the Division of Health Plan Innovation at the Center for Medicare and Medicaid Innovation, wrote that the agency did not expect sponsors to have to replace their current data collection systems or contract with new vendors unless they so desire.² Data in existing proprietary systems can be mapped to SNOMED CT codes when sponsors prepare EMTM encounter data for submission. Mary Jo Carden, Vice President of Government and Pharmacy Affairs at the Academy of Managed Care Pharmacy (AMCP), says, "We understand from health plans, PDPs, and pharmacy organizations that SNOMED codes are the wave of the future. But it currently is a challenge to use those codes for MTM services because of a lack of standardization in defining the services provided with a link to the codes." AMCP is working with the Pharmacy Quality Alliance (PQA), which has already linked SNOMED codes to identify drug therapy problems for measures, and with the Pharmacy Health Information Technology Collaborative to link services to SNOMED codes. To allow time for participants in the EMTM program to adopt the SNOMED codes, AMCP has asked for a delay in the CMS's initial reporting requirement from July 2017 until the fourth guarter of 2017.

Groups such as the PQA are working with the agency to develop the technical specifications for the proposed monitoring measures, that is, the numerator and denominator for each. Beyond the EMTM test model, those measures may lead to quality measures that the CMS can use when assigning star ratings to Part D plans. To date, there is only one quality measure for MTM programs: the comprehensive medication review (CMR) completion rate. The agency made that the first MTM measure in its star rating system starting in 2016. "That is a very process-driven measure, and there is a need to develop other measures that show the quality of MTM programs," states Julie Kuhle, Vice President of Measure Operations for PQA.

With regard to SNOMED CT codes, Kuhle says it is likely that pharmacies already working with MTM vendors will see a seamless transition if their vendor is contracted with a PDP to work in the model program. Physician practices and probably many hospital outpatient pharmacies with access to electronic health records should be able to capture SNOMED CT data without too much effort. Community pharmacies not currently working with MTM vendors may face both additional expense and barriers related to workflow, neither of which will be insurmountable, but neither will they be totally smooth sailing.

A PDP that participates in the model will either work the EMTM program internally or hire a vendor such as OutcomesMTM. Many MTM vendors already capture billing and clinical documentation data in Web-based systems and can easily map that data to SNOMED CT codes. If the PDP decides not to hire an MTM vendor, the Part D plan sponsor would need to develop a clinical documentation tool to scale across a pharmacy network. "That in and of itself is a very large project," states Frank of OutcomesMTM. "Then the plan must integrate SNOMED CT codes into that system to meet the model reporting requirements."

"This is the first opportunity the pharmacy industry has to adopt standardized codes. The mapping of SNOMED CT codes to EMTM activities isn't hard. The challenge is assuring consistency across the pharmacy landscape," explains Frank. "Different PDPs and MTM vendors may have their own proprietary data systems and could map different activities to the same SNOMED CT code. When identifying best practices, this lack of consistency becomes a problem."

Problems With the MTM Program

For pharmacists, the EMTM model presents the chance to prove they can make an important contribution to improving seniors' drug choices, medication adherence, and health outlook, ultimately extending and saving lives and saving both the Part D insurance companies and the federal government dollars. There is already scattered evidence that this is true. In 2013, the CMS found that Part D MTM programs substantially improved medication adherence for beneficiaries with congestive heart failure, chronic obstructive pulmonary disease (COPD), and diabetes.3 The study found that this led to significant savings in hospital costs, including reductions of nearly \$400 to \$525 in overall hospitalization costs per patient for beneficiaries with diabetes and congestive heart failure. The report also showed that these services can reduce costs in the Part D program as well. The best-performing plan saved an average of \$45 per diabetes patient on the Part D side.³

Nearly 40 million Medicare beneficiaries are enrolled in a Medicare-sponsored plan that provides prescription drug coverage, with approximately 24 million Medicare beneficiaries accessing their prescription drugs from a stand-alone PDP operating within the Part D outpatient benefit. Those PDPs, operating in every state, must offer MTM services to plan members who meet three criteria: more than one chronic condition, taking multiple drugs (between two and eight), and incurring annual costs for covered Part D drugs above a cost threshold (\$3,138 in 2015). Those criteria fit about 25% of Part D recipients. But only 11% receive MTM services, and those services are all over the board. Eighty-five percent of programs target beneficiaries with three or more chronic illnesses, and 52% of programs target beneficiaries using eight or more drugs, according to Joel White, President of Prescriptions for

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a Healthy America, which is composed mostly of pharmaceutical and pharmacy companies. The enhanced model will allow PDPs to segment patients who have only diabetes, for example.

Currently, sponsors must offer a minimum level of MTM services to all eligible beneficiaries, including an annual CMR, which is an interactive person-to-person or telehealth consultation performed by a pharmacist or other qualified provider for the beneficiary with an individualized, written summary in the CMS's standardized format; and quarterly targeted medication reviews with follow-up interventions when necessary. The vast majority of plans—95.8% of programs—offer the interactive CMR consultation via telephone, while 58.2% of programs also offer face-to-face CMRs and 15.9% of programs offer CMRs through telehealth technologies.

The key word above is "offer." MTM-eligible individuals do not have to participate in the program; they can opt out. Only about 1% of beneficiaries in all of Part D receive CMRs. Plans are chary of spending lots of money to convince reluctant members otherwise. Those plan members who do participate are offered a range of services, which the plan may or may not coordinate with the member's physician and pharmacist. "After almost a decade of experience, we are concerned that the Part D MTM program as it is currently structured—delivered primarily through prescription drug plans and detached from the patient's health care team and medical records—fails to support this patient-centric comprehensive approach and will never fully realize the full potential of effective, team-based medication management in terms of improved outcomes and lower costs," states the American College of Clinical Pharmacy.

Will Incentives Lead to Greater Use of Pharmacies?

Besides the upfront investment and the promise of a premium subsidy at the end of five years, the enhanced model program will offer some administrative and operational incentives. For example, MTM costs are traditionally considered administrative costs and counted against a plan's medical loss ratio (MLR). "It is a further reason that plans feel the financial need to minimize the investment in these programs," says Tim Gronniger, Director of Delivery System Reform for the CMS. That will change for participants in the enhanced model, in which expenses devoted to MTM marketing and services will be treated as quality improvement activities. They will not be counted in the MLR calculation.

The direct financial subsidies from the CMS will ostensibly encourage PDPs to invest in MTM programs. Gronniger hopes some of that spending is on recruitment of community pharmacies. "This model provides potential opportunity for plans to invest in pharmacist-based MTM programs at the local level where the opportunity for direct beneficiary engagement is greatest," he explains. "Pharmacists might be well positioned to identify candidate beneficiaries starting new medications with risky side effect profiles, to help patients receiving medication assistance devices, such as pill splitters or mobile phone reminder apps, synchronized refills to provide home delivery and cost-sharing assistance, and to provide counseling advice."

Jesse McCullough, Director of Field Clinical Services for Rite Aid, explains that, in some states, pharmacists are allowed to perform blood tests, which would allow them to intervene and collaborate with prescribers to adjust therapies more appropriately. "However, as it is right now, we do not have the capacity to be able to bill for services like that, which would be very simple and very timely interventions where the patient's therapy is adjusted in a more timely manner," he states.

Congress Considers Other Part D Pharmacist Incentives

There is significant support in Congress to do the enhanced model one better by allowing all PDPs to reorient their programs—no pilot program needed—to target just one chronic condition as long as it is cardiovascular disease, COPD, hyperlipidemia, or diabetes. A Senate bill (S. 776) introduced by Senator Pat Roberts (R-Kansas) has an approximately equal number of Democratic and Republican supporters. However, it was introduced in March 2015 and sent to the Senate Finance Committee, where it has languished.

Another bill introduced by Representative Brett Guthrie (R-Kentucky) in January 2015 would allow Medicare to pay for pharmacist services that it would otherwise pay for when billed by a physician as "incident" to his or her services. The payments could only be made to pharmacists in a health professional shortage area, medically underserved area, or medically underserved population area. The bill—the Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592)—has 285 cosponsors in the House, is strongly bipartisan like Roberts' Senate bill, and again is stuck in the four House committees it was referred to. No action has been taken anywhere, and none is expected.

Asked why what appears to be such a popular bill has been stuck in cement in the House, Maria Kim, spokeswoman for Representative Guthrie, states, "We've spent this time building strong, bipartisan support and are currently awaiting a cost estimate from CBO [Congressional Budget Office]. Once that comes back, we're hopeful that we will be able to move the bill forward. With such an overwhelming number of cosponsors, we are in a good position to advance the bill when there is an opportunity."

2017 Call Letter Changes

The requirements the CMS is setting for the EMTM model are really the big news for the Part D program in 2017. The 2017 Call Letter⁶ doesn't add very much to MTM requirements generally, and it is only guidance in any case. The CMS will issue a final rule on Part D changes later this year, which the agency will be able to enforce, and those changes will probably track fairly closely to what was in the final Call Letter.

The good news for the pharmacy industry is what was *not* in the final 2017 Call Letter. The agency decided to dump one change it had proposed in the draft Call Letter: that PDPs implement soft and hard formulary-level cumulative morphine equivalent dose at the point-of-sale (POS) edits beginning January 1, 2017. This is one of a number of responses to the opioid epidemic in the 2017 Call Letter. Soft edits give PDPs the option of deciding whether to fill the prescription; hard edits prohibit filling prescriptions of a certain quantity over a certain time frame. The AMCP and others disputed the need for hard edits, whose specifications PDP P&T committees would have been responsible for developing. The AMCP was concerned that the CMS was focusing on POS edits to address the opioid epidemic, which the group thought was a reactive

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approach. Instead, it wants the CMS to focus on adopting proactive means of identifying at-risk beneficiaries, such as lock-in programs and expanding access to state prescription drug monitoring program data to health plans.

Of course, at-risk beneficiaries are also the targets of the EMTM model, except that those being pinpointed will have costly medical conditions, such as diabetes and coronary heart disease. If Part D plans are able to better find and help those on the cusp or in the throes of opioid addiction—people often headed for bad outcomes—and also establish higher-value MTM programs, they will be on their way to a new era where "value" becomes a Part D watchword.

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